

**TAB 21**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
MDL NO. 1456 / CIVIL ACTION NO. 01-12257-PBS

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IN RE: PHARMACEUTICAL INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION

- - - - - x  
THIS DOCUMENT RELATES TO:  
UNITED STATES OF AMERICA, EX REL.  
VEN-A-CARE OF THE FLORIDA KEYS, INC.

vs.

BOEHRINGER INGELHEIM CORPORATION, ET AL.

CIVIL ACTION NO. 07-10248-PBS

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CAPTIONS CONTINUED ON FOLLOWING PAGES  
Videotape deposition of MARK SHAFFER, taken  
pursuant to the Federal Rules of Civil Procedure,  
before Melissa J. Kelly, RPR, CRR, Licensed  
Shorthand Reporter #00307, and Notary Public within  
and for the State of Connecticut, held at the  
Sheraton Danbury Hotel, 18 Old Ridgebury Road,  
Danbury, Connecticut, on May 21, 2008, at 10:09 a.m.

<p style="text-align: right;">46</p> <p>1        What I said at the beginning of the      2 deposition is that Roxane's position is that Ven-      3 A-Care does not have any independent claims or      4 independent rights to ask questions that are not      5 related to the government claims and on behalf of      6 the government. And so we object to Ven-A-Care's      7 lawyers questioning the witness unless it has      8 been authorized to do so on behalf of the      9 government and in pursuant of the government's      10 claims other than original resource-type      11 questions.</p> <p>12       So I just wanted to get on the record      13 that the government has designated Ven-A-Care to      14 take questions in this deposition on behalf of      15 the government in pursuit of those claims and      16 there won't be duplicative questions between what      17 Ven-A-Care's lawyers will be asking of Mr.      18 Shaffer and any questions that the government may      19 have.</p> <p>20       MS. OBEREMBT: As Roxane knows, we      21 believe their position is completely inconsistent      22 with explicit statutory language under the false</p>	<p style="text-align: right;">48</p> <p>1 for the record we'll let the proceedings proceed      2 with Ven-A-Care's lawyers asking the questions      3 subject to our objection that that -- those      4 questions would be on behalf of and in pursuit of      5 the government's claims other than any original      6 source-type questions, which we do believe Ven-A-      7 Care has an independent right to ask.</p> <p>8        MR. KILMAN: This is Matt Kilman from      9 the State of California. And if I could just      10 also put on the record that California cross      11 noticed the deposition for the purpose of      12 judicial economy and pursuant to the CMO and      13 RMVL, and we reserve the right to ask our own      14 line of questions.</p> <p>15       MS. RIVERA: Okay.</p> <p>16       MS. POLLACK: Okay.</p> <p>17       MS. ROGERS: And that would be the same      18 for the state of Florida.</p> <p>19       MS. RIVERA: Understood.</p> <p>20 BY MS. POLLACK:</p> <p>21 Q. Okay. Mr. Shaffer, we're going to go      22 back to the sales meetings in 1994 through 1998.</p>
<p style="text-align: right;">47</p> <p>1 claims act. And the only thing that I wanted to      2 say is that we're not going to have duplicative      3 questioning of the witness.</p> <p>4        MS. RIVERA: Okay. So you're not      5 willing to say that Ven-A-Care has been      6 authorized on behalf of the government to ask      7 questions on behalf of government claims?</p> <p>8        MS. OBEREMBT: Ven-A-Care is a      9 plaintiff in this matter and is such able to ask      10 questions both on their own behalf, and in this      11 instance we have asked relator's counsel to be      12 the lead questioner on this deposition.</p> <p>13       MS. RIVERA: On behalf of both Ven-A-      14 Care and the government; is that correct?</p> <p>15       MS. OBEREMBT: If that's a meaningful      16 statement to you, you're welcome to make that,      17 but Ven-A-Care we believe has an independent      18 right to ask questions here.</p> <p>19       In this deposition they will be taking      20 the lead, and I do not intend to be asking      21 questions.</p> <p>22       MS. RIVERA: Okay. Well, as I said,</p>	<p style="text-align: right;">49</p> <p>1        Did BIPI personnel attend the same      2 sales meetings as the Roxane personnel?</p> <p>3        A. No, they did not.</p> <p>4        Q. Did you get involved in providing any      5 of the materials that were presented at those      6 sales meetings in that time frame?</p> <p>7        A. I'm not sure what you mean "involved."</p> <p>8        Q. Well, as the area sales manager, would      9 you help set the agenda for the meetings?</p> <p>10       A. No.</p> <p>11       Q. Who was --</p> <p>12       A. That was set by marketing.</p> <p>13       Q. By marketing?</p> <p>14       A. Marketing would set the agenda, right.</p> <p>15       Q. Okay. And who would that be? Would      16 that be Tom Via or --</p> <p>17       A. Over that time frame there were a      18 number of different individuals in the marketing      19 department at Roxane.</p> <p>20       Q. Would you make presentations at any of      21 these sales meetings?</p> <p>22       A. We would normally at sales meetings</p>

<p style="text-align: right;">50</p> <p>1 <b>have breakouts with our individual teams, and we</b>      2 <b>would basically facilitate the meeting.</b></p> <p>3 Q. You wouldn't make presentations to the      4 entire group that was --</p> <p>5 <b>A. No. That was basically marketing and</b>  <b>the home office.</b></p> <p>7 Q. Okay. And which home office was that?</p> <p>8 <b>A. Roxane Laboratories.</b></p> <p>9 Q. In your position as the senior area      10 sales manager, did you ever get involved with      11 pricing of Roxane drugs?</p> <p>12 <b>A. No, I didn't.</b></p> <p>13 MS. RIVERA: Object to form.</p> <p>14 BY MS. POLLACK:</p> <p>15 Q. Who set the pricing for the Roxane      16 drugs?</p> <p>17 <b>A. Pricing was set by Roxane, the company.</b></p> <p>18 Q. But what department or group?</p> <p>19 <b>A. I would think marketing set the pricing</b>  <b>or had some say-so in the pricing.</b></p> <p>21 Q. Anybody else involved in that process?</p> <p>22 MS. RIVERA: Object to form.</p>	<p style="text-align: right;">52</p> <p>1 will.</p> <p>2 Q. But you said you also and the people      3 who worked for you would also call on pharmacies;      4 is that correct?</p> <p>5 <b>A. Occasionally, yes.</b></p> <p>6 Q. When you were the area sales manager,      7 did you get involved in contracting at all?</p> <p>8 <b>A. No, I didn't.</b></p> <p>9 Q. Did you call on customers like long-      10 term care facilities?</p> <p>11 <b>A. I don't recall. At Roxane</b>  <b>Laboratories?</b></p> <p>13 Q. Yes.</p> <p>14 <b>A. I don't recall if we called on long-</b>  <b>term care facilities. I don't think we did.</b></p> <p>16 Q. Did you call on any Hospice customers?</p> <p>17 <b>A. We did call on Hospice.</b></p> <p>18 Q. As part of Roxane?</p> <p>19 <b>A. As part of Roxane.</b></p> <p>20 Q. And that would be to sell the drugs you      21 identified earlier?</p> <p>22 <b>A. Yes.</b></p>
<p style="text-align: right;">51</p> <p>1 THE WITNESS: I don't know.</p> <p>2 BY MS. POLLACK:</p> <p>3 Q. Well, as a sales representative, if you      4 were out in the field and you learned of a price      5 that a competitor was charging for a competitive      6 drug, wouldn't you provide that information to      7 the marketing folks?</p> <p>8 <b>A. There was communication that would come</b>  <b>back into the home office, yes.</b></p> <p>10 Q. Was that part of your job duties, to      11 provide that sort of information if you learned      12 it?</p> <p>13 <b>A. Not one of my priorities, no.</b></p> <p>14 Q. But you would do it?</p> <p>15 <b>A. It would depend on the situation.</b></p> <p>16 Q. Okay. Would you direct the people who      17 reported to you that if they learned of pricing      18 of competitive products to report that back to      19 you?</p> <p>20 <b>A. Not really. I mean, our</b>  <b>responsibilities were focused with the physician</b>  <b>in driving prescriptions -- in detailing, if you</b></p>	<p style="text-align: right;">53</p> <p>1 Q. How did marketing interact with the      2 sales managers?</p> <p>3 <b>A. At sales meetings, like I mentioned</b>  <b>earlier, there would be interaction. There may</b>  <b>have been occasional conference calls or other</b>  <b>meetings where we might have run into the</b>  <b>marketing folks. But for the most part, as I</b>  <b>mentioned, they were inside at the home office</b>  <b>and we were in the field; so we were separate.</b></p> <p>10 Q. What types of information would they      11 provide on these telephone calls?</p> <p>12 <b>A. It could be a vast array of information</b>  <b>on our products, on updates, on promotional</b>  <b>materials, on competitive information.</b></p> <p>15 Q. Would that competitive information      16 include the prices that competitors were charging      17 for similar drugs?</p> <p>18 <b>A. I don't recall. It could have.</b></p> <p>19 Q. Did you ever get marketing materials      20 that talked about the prices your competitors      21 were charging for the competitive drugs?</p> <p>22 <b>A. There may have been some, yes.</b></p>

15 (Pages 54 to 57)

<p style="text-align: right;">54</p> <p>1 Q. Was that a pretty regular thing, that 2 you would get updates on the competitors' prices? 3 <b>A. No. Because I think most of our</b> <b>4 efforts were focused on our activities and our</b> <b>5 messaging with our customer.</b></p> <p>6 Q. Now, you said in 1999 you became the 7 director of palliative care sales; is that 8 correct?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. What did that entail?</p> <p>11 <b>A. We had started up a new separate sales</b> <b>12 team to continue to call on oncologists and pain</b> <b>13 management physicians along with Hospice,</b> <b>14 basically promoting certain products to</b> <b>15 healthcare professionals to educate them on those</b> <b>16 products for -- to help with palliative care or</b> <b>17 the quality of life in pain control.</b></p> <p>18 Q. Did you also call on retail pharmacies?</p> <p>19 <b>A. Occasionally we did.</b></p> <p>20 Q. What percentage of a salesman's efforts 21 would you say were spent calling on retail 22 pharmacies?</p>	<p style="text-align: right;">56</p> <p>1 Q. Were there any interim meetings of the 2 area managers?</p> <p>3 <b>A. No. Because our territories were so</b> <b>4 large.</b></p> <p>5 Q. During the time that you were the 6 senior area sales manager, did Roxane launch any 7 new drugs?</p> <p>8 MS. RIVERA: Object to form.</p> <p>9 THE WITNESS: As I had mentioned 10 earlier, Viramune was a new drug that we 11 launched.</p> <p>12 BY MS. POLLACK:</p> <p>13 Q. Anything else besides Viramune?</p> <p>14 <b>A. I can't recall.</b></p> <p>15 Q. Was there a separate launch meeting to 16 talk about Viramune?</p> <p>17 <b>A. I believe there was.</b></p> <p>18 Q. And did that meeting include training 19 materials for the sales representatives?</p> <p>20 <b>A. I believe it did.</b></p> <p>21 Q. Would there be presentations made by 22 various people to talk about the drug?</p>
<p style="text-align: right;">55</p> <p>1 <b>A. Fifteen, maybe 20 percent.</b></p> <p>2 Q. Now, what drugs were sold by this 3 palliative care group?</p> <p>4 <b>A. Roxanol, Oramorph SR, Marinol and I</b> <b>5 believe Roxicodone.</b></p> <p>6 Q. Did you also sell a drug called 7 Duraclon?</p> <p>8 <b>A. We did sell Duraclon for a short period</b> <b>9 of time.</b></p> <p>10 Q. Any other drugs that you can recall?</p> <p>11 <b>A. I can't recall any other drugs.</b></p> <p>12 Q. Roxanol, Roxanol T, was that a drug 13 that you sold in this group?</p> <p>14 <b>A. Yes. Roxanol T was very similar to</b> <b>15 Roxanol.</b></p> <p>16 Q. And did this group also have sales 17 meetings of the type we discussed earlier?</p> <p>18 <b>A. Yes, we did.</b></p> <p>19 Q. Were they quarterly; was there any set 20 time frame?</p> <p>21 <b>A. I don't recall. I want to think they</b> <b>22 were three times a year.</b></p>	<p style="text-align: right;">57</p> <p>1 <b>A. As with most sales meetings, yes.</b></p> <p>2 Q. Were there any drugs launched while you 3 were head of the palliative care group?</p> <p>4 <b>A. There was an extension of Roxicodone</b> <b>5 that was launched on different strengths.</b></p> <p>6 Q. And that was the 15 milligram and the 7 30 milligram tablets?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. Were those drugs launched pursuant to a 10 new drug application that had been filed by 11 Roxane?</p> <p>12 <b>A. I don't recall. I'm not sure.</b></p> <p>13 Q. Were there any clinical trials done in 14 connection with those two new products?</p> <p>15 <b>A. I don't recall.</b></p> <p>16 Q. You don't know. It's possible?</p> <p>17 <b>A. There may have been. I don't recall.</b></p> <p>18 Q. Now, you said in 2000 Roxane divested 19 the palliative care drugs; is that correct?</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. Do you know why that occurred?</p> <p>22 <b>A. I do not know why we basically divested</b></p>

<p style="text-align: right;">222</p> <p>1 MS. RIVERA: Object to form.      2 THE WITNESS: Right.      3 MS. RIVERA: What do you mean by      4 "Boehringer Ingelheim"?      5 BY MS. POLLACK:      6 Q. The Boehringer Ingelheim worldwide      7 organization, right?      8 MS. RIVERA: Object to form.      9 BY MS. POLLACK:      10 Q. You can answer.      11 A. It's part of Boehringer Ingelheim.      12 Q. In fact, all the stationery says right      13 in the upper right-hand corner "Boehringer      14 Ingelheim"; isn't that correct?      15 A. I'm not sure which stationery you're      16 referring to.      17 Q. Okay. You can look at the documents we      18 looked at today.      19 Okay. If you look at page 29, it lists      20 the key strategies; and the first one is "target      21 distribution to high-volume C2 analgesic      22 pharmacies," correct?</p>	<p style="text-align: right;">224</p> <p>1 THE WITNESS: Again, that's -- you keep      2 bringing that up, and that's not how I'm looking      3 at it.      4 BY MS. POLLACK:      5 Q. How are you looking at it?      6 A. I'm looking at it that the product was      7 priced so pharmacies would bring the product in      8 and we would not be substituted because of the      9 new 15 and 30 milligram strengths being available      10 and prescriptions are being driven.      11 Q. Okay. Now, Roxane at that time      12 manufactured and sold a 5 milligram Roxicodone      13 tablet; is that correct?      14 A. Yes, correct.      15 Q. So you could have been substituted with      16 the Roxane product under your scenario, correct?      17 A. It could have been, yes.      18 Q. Okay. Now we get to page 35 which is      19 also Shaffer 1486, and this outlines the pricing      20 approach, doesn't it?      21 A. That's what the document says, "pricing      22 approach."</p>
<p style="text-align: right;">223</p> <p>1 A. Correct.      2 Q. That's what you just mentioned, is to      3 get the product into the pharmacies, right?      4 A. Yup.      5 MS. RIVERA: Sorry. What page are you      6 on?      7 MS. POLLACK: 1480. It's 29.      8 MS. RIVERA: Okay. Thank you.      9 BY MS. POLLACK:      10 Q. And also listed is price for favorable      11 retail reimbursement, correct?      12 MS. RIVERA: Object to form. What is      13 the question? That's what it says?      14 BY MS. POLLACK:      15 Q. I'm asking: One of the key strategies      16 listed here was price for favorable retail      17 reimbursement?      18 A. That's what it has on here, yes.      19 Q. And that was to provide more profit to      20 the pharmacy to fill a prescription with the 15      21 and 30 milligrams, correct?      22 MS. RIVERA: Object to form.</p>	<p style="text-align: right;">225</p> <p>1 Q. Okay. And it says, "Set AWP and WAC at      2 a level favorable to the average for oxycodone      3 class for equivalent number of 5 milligram      4 tablets," right?      5 A. Yes.      6 Q. "Equivalent or higher reimbursement      7 levels, AWP minus a percentage."      8 A. That's what it says.      9 Q. And "minimal need for contract      10 pricing"?</p> <p>11 A. That's what it says, yes.      12 Q. Wasn't in fact -- weren't in fact these      13 two strengths sold at contract prices to GPOs?      14 A. I don't recall. I -- because the      15 product was only on the market for several      16 months, and I don't recall if we put that on      17 contracts or not.      18 Q. Well, wasn't the product on the market      19 for at least a year?      20 A. It may have been. Let me rephrase my      21 comment.      22 It was -- while we were at Roxane</p>

<p style="text-align: right;">226</p> <p>1 <b>Laboratories, that fall the division was 2 dissolved, I believe, in November. So our 3 activity was limited to two months, I believe, 4 with this product.</b></p> <p>5 Q. November or at the end of the year that 6 the division was --</p> <p>7 <b>A. I think it was in -- at the end of 8 November.</b></p> <p>9 Q. Okay. If you look at page 1489, it 10 says: "For contracting, limit discounts to a 11 maximum of 10 percent to provide an incentive to 12 substitute 15 milligram for three 5 milligram or 13 30 milligram for six 5 milligram."</p> <p>14 Does that indicate that the contract 15 price would be up to 10 percent off the WAC?</p> <p>16 <b>A. Again, I wasn't involved with pricing. 17 I don't recall the contract pricing.</b></p> <p>18 Q. And the other bullet on this point 19 says: "Select only accounts that can move market 20 share."</p> <p>21 What does that mean?</p> <p>22 <b>A. I'm not sure what that bullet point</b></p>	<p style="text-align: right;">228</p> <p>1 Q. And the goal, of course, was to 2 increase your market share, right? That's what 3 the sales force was supposed to do?</p> <p>4 <b>A. I think that's a fair statement.</b></p> <p>5 Q. How was the sales force compensated?</p> <p>6 <b>A. We were compensated, like a lot of 7 pharmaceutical companies, by bonuses. I believe 8 we were on a quarterly basis based on goal 9 attainment, quota attainment.</b></p> <p>10 Q. And when you say "bonus," was that a 11 commission or --</p> <p>12 <b>A. It was an extra bonus commission.</b></p> <p>13 Q. Based on amount of sales; is that what 14 you're saying?</p> <p>15 <b>A. Based on goal attainment, yes.</b></p> <p>16 Q. Was that an increase in sales over last 17 year? How was that calculated?</p> <p>18 <b>A. I don't recall. I wasn't involved with 19 setting of those goals.</b></p> <p>20 Q. But you had one every year?</p> <p>21 <b>A. Absolutely.</b></p> <p>22 Q. And as the manager of the palliative</p>
<p style="text-align: right;">227</p> <p>1 <b>means under "strategy."</b></p> <p>2 Q. Was market share a concept that was 3 discussed at the palliative care sales meetings?</p> <p>4 <b>A. I don't recall. I mean, other than 5 your initial slides from marketing talking 6 historically about the product and the growth of 7 the product, trends of the product in share, 8 other than that, I don't recall.</b></p> <p>9 Q. So you would look at what percent of 10 the coating market was sold by Roxane and sold by 11 Purdue Frederick or other competitors; is that 12 correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. And then you would break it down to 15 each of the codone products that were sold by 16 Roxane, what percentage product had of the total 17 market?</p> <p>18 <b>A. I don't believe the specific -- I don't 19 remember the specifics with the breakdown, but 20 that's --</b></p> <p>21 Q. The type of thing you looked at.</p> <p>22 <b>A. -- the type of thing.</b></p>	<p style="text-align: right;">229</p> <p>1 care sales force, you had one too, correct?</p> <p>2 <b>A. I don't recall my -- what my plan was 3 like compared to the sales representatives 4 specifically.</b></p> <p>5 Q. When the sales representatives got 6 these bonuses, were there occasions where a 7 portion of their bonus was based on selling a 8 particular drug as opposed to the total sales 9 that they were responsible for?</p> <p>10 <b>A. Yes. The bonuses -- the plans were set 11 up according to promote a product.</b></p> <p>12 Q. So some years Roxane would be promoting 13 product X more than maybe the rest of the product 14 line?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. And page 39 indicates as part of the 17 pricing strategy was "a Medicaid reimbursement 18 plan which included submitting requests for the 19 Roxicodone 15 and 30 milligram tablets to be 20 added to state Medicaid formularies." Do you see 21 that?</p> <p>22 <b>A. I see it on here.</b></p>